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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/727,464

12/04/2000

Gal Ben David

00/21303

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7590  
Martin D. Moynihan  
PRTSI, Inc.  
P.O. Box 16446  
Arlington, VA 22215

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EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT

PAPER NUMBER

3737

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/727,464	<b>Applicant(s)</b> DAVID ET AL.	
	<b>Examiner</b> JOHN F. RAMIREZ	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/26/06.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-147 is/are pending in the application.
- 4a) Of the above claim(s) 9-16, 18-22, 24-25, 29-33, 35-36, 41-45, 47-48, 50-61, 64-71, 73-76, 78-121, 123-132 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 17, 23, 26-28, 34, 37-40, 46, 49, 62, 63, 72, 77, 122 and 133-147 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Response to Arguments***

Applicant's arguments filed on 12/26/06 have been fully considered but they are not persuasive. Acknowledgement has been made to the terminal disclaimer filed in order to overcome the double patenting rejection, therefore it is herein withdrawn. Applicant alleges that the Weinberg patent does not teach a flexible connection between the cameras. However, the examiner disagrees with applicant's comments. The Weinberg et al. illustrates in Figure 9 that the cameras 142 and 156 are connected to a data acquisition device 162 via cables as shown in the figure. (note: the cameras have a common connector device e.g. the ports in the circuit device, therefore they are physically connected to each other). Therefore, the rejection is maintained and made final.

***Drawings***

The drawings are objected to because some of the figures numbers are not label correctly. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

Art Unit: 3737

made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 49 is objected to because of the following informalities: The sentence **"Please add a pointing device for the open surgery application"** appears to have been inadvertently included in the claim. Appropriate correction is required.

Furthermore the "hand-held" gamma camera as argued is not claimed in the current claims. Therefore, the rejection is maintained and made final.

Claim 77 is objected to because of the following informalities: Claim is depending on a cancelled claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 3737

Claims 17,23,28,34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "the at least one other imaging modality" is considered to be new matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined

Art Unit: 3737

under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 1-8, 17, 23, 26, 28, 34, 37, 39-40, 46, 49, 62-63, 72, and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Weinberg (US 6628984).**

Weinberg discloses a system including a position sensor for determining the position and angulation for the detector in relation to a gamma ray emission source (col 2, lines 34- 36). The system further includes a moveable detector capable of detecting radiation and a processor for integrating the position of the detector with the information detected by the detector (col 2, lines 30-40). Radiotracers are used, such as tumor-seeking radiotracers, as the source of radioactivity (col 1, 25-27). The detector is sensitive to radiation at multiple locations (col 2, lines 59-66), or spatially sensitive. Additionally, the beam is narrowed by an aperture (figure 1, element 7). The position tracking system (figure 1, element 2) is based on an electromagnetic field (col 6, lines 12-19). The detector and tracking system are connected, as shown in figure 1 (elements 2 and 6). Registration may be done with data from anatomic imaging modalities, which projects the position of the source into a second system of coordinates (col 9, lines 35-63). The use of position sensors on the radioactive emission detector, which are visible in the imaging modality, allows the two position tracking systems to be a single position tracking system. It is inherent in the registration process that transformations may be mapped from coordinate system 1 to coordinate system 2 or vice versa. Multiple coordinate systems are also shown in

Art Unit: 3737

figure 3. The imaging modality is disclosed exemplarily as either an ultrasound or a magnetic resonance imaging system. A data acquisition device and computer are included to do necessary computations and processing involved with the system and method steps presented. A surgical instrument, such as a needle, is used in connection with the detector (col 10, lines 21- 37). The needle has its own system of coordinates, but is in rigid registration with the detector system (figure 10 and col 10, line 34). Alternatively, the needle may have a separate position sensor (col 10, lines 38-42). A second detector may be used to refine the position and eliminate some of the effects of Compton scattering (figure 8, elements 128 and 134) either in the same detector system or by the inclusion of a second detector and positioning system (figure 7). The two detector systems are physically connected via a flexible connector in the form of a cord (figure 9). (note: the cameras have a common connector device e.g. the ports in the circuit device, therefore they are physically connected to each other). Alternatively, a PET or SPECT scanner may be used, which are positron radiation detectors (col 11, lines 35-40).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 27, 38, 122, and 133 rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg in view of Wainer, et al (US 5871013).**

Weinberg, as discussed above, substantially discloses the invention as claimed including that a radiotracer is used, such as a tumor-seeking radiotracer.

However, Weinberg fails to explicitly disclose the use of particular radiotracers.

Wainer also discloses a system and method for registration of nuclear medicine images including both functional and structural images and further discloses the use of Tc99 (col 6, line 43) for acquiring images of the liver. It is well known in the medical imaging art that radiotracers may be chosen to target specific anatomic regions in the body. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Weinberg in light of the teachings in the reference by Wainer in order to acquire images of a specific target, namely the liver.

**Claims 134,140, 146-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberg in view of Bennett, et al (US Statutory Invention Registration H12).** Weinberg, as discussed above, substantially discloses the invention as claimed. Although Weinberg discloses the use of two cameras connected together by a cable, Weinberg does not explicitly disclose the use of a hinge, an articulated system of arms and joints.

Bennett et al. disclose an imaging system for a variety of studies and further discloses two cameras that are rotated and the position of the camera's angle is tracked (see fig. 8, abstract, col. 5, lines 58-66).



Art Unit: 3737

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Weinberg in light of the teachings in the reference by Bennett et al. to include the above discussed enhancements, because such improvement would improve resolution for certain clinical situations.

With respect to claims 135-139 and 141-145, Weinberg places the camera within a body cavity or to be used intraoperatively, so that one or many of the camera heads can be in a body cavity and other camera heads be outside the body cavity, or for all camera heads to be inside the body cavity as shown in figures 7-10, to derive a three dimensional representation of the lesion based on the integration of information from one area of interest to another (abstract, col. 2 lines 4-40).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

Art Unit: 3737

the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/  
Supervisory Patent Examiner, Art  
Unit 3737

Art Unit: 3737

/J. F. R./

Examiner, Art Unit 3737